

ORIGINAL ARTICLE

Living donor liver transplant candidate and donor selection and engagement: Meeting report from the living donor liver transplant consensus conference

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Abstract

Introduction: Living donor liver transplantation (LDLT) is a promising option for mitigating the deceased donor organ shortage and reducing waitlist mortality. Despite excellent outcomes and data supporting expanding candidate indications for LDLT, broader uptake throughout the United States has yet to occur.

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[Correction added on 18 April 2023, after the
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 has been corrected]

Methods: In response to this, the American Society of Transplantation hosted a virtual consensus conference (October 18–19, 2021), bringing together relevant experts with the aim of identifying barriers to broader implementation and making recommendations regarding strategies to address these barriers. In this report, we summarize the findings relevant to the selection and engagement of both the LDLT candidate and living donor. Utilizing a modified Delphi approach, barrier and strategy statements were developed, refined, and voted on for overall barrier importance and potential impact and feasibility of the strategy to address said barrier.

Results: Barriers identified fell into three general categories: 1) awareness, acceptance, and engagement across patients (potential candidates and donors), providers, and institutions, 2) data gaps and lack of standardization in candidate and donor selection, and 3) data gaps regarding post-living liver donation outcomes and resource needs.

Conclusions: Strategies to address barriers included efforts toward education and engagement across populations, rigorous and collaborative research, and institutional commitment and resources.

KEYWORDS

living donor liver transplant, living donor transplant recipient, living liver donor

1 | INTRODUCTION

Liver transplantation is the only curative therapy for patients with decompensated liver disease, providing opportunity for improved survival and quality of life.^{1,2} However, access to liver transplantation is limited with 17%–25% of candidates removed from the waitlist due to deterioration or death^{3,4} and certain populations (e.g., racial/ethnic minority groups, women) are at a disproportionately greater risk of being delisted before receiving a deceased donor liver.^{5,6}

Living donor liver transplantation (LDLT) is a promising option for mitigating the deceased donor liver shortage and consequently reducing liver transplant waitlist mortality. Current estimates of donor mortality are less than 0.3%–0.5%^{7–9} (comparable to living kidney donors^{10,11}). The majority of post-operative complications are Clavien grades I or II,¹² and the vast majority of living liver donors reporting they would donate again.^{8,13} Benefits to the recipient include earlier transplant at lower Model for End-Stage Liver Disease scores (MELD/MELD-Na), which ultimately significantly reduces waitlist mortality risk, and superior long-term outcomes.^{14–16} Yet broader utilization across the United States (US) has lagged despite the need. This is due, at least in part, to a few highly publicized donor deaths early in the US experience.¹⁷ The consequence has been reluctance or even resistance to LDLT across clinical communities, resulting in a lack of public discourse or awareness of LDLT.

While every effort should be made to minimize donor risk relative to recipient benefit (or double equipoise), increasing evidence suggesting improved donor safety and broader candidate selection criteria and benefit supports a paradigm shift to move from absolute risk avoidance

to evidence-based attributable risk stratification and mitigation.¹⁸ To that end, the American Society of Transplantation (AST) initiated a consensus conference to identify and address barriers to the safe expansion of LDLT in the US. This manuscript is a work product of the American Society of Transplantation LDLT Consensus Workgroup, which included the Living Donor Community of Practice (LDCOP), Liver and Intestinal Community of Practice (LICOP), and the Psychosocial and Ethics Community of Practice (PSECOP). Various workgroups were formed to identify current barriers within specific domains across the process of LDLT. The report herein represents two workgroups focused on selection and engagement of both candidates and living donors.

2 | METHODS

In early 2021, the LDCOP, LICOP, and the PSECOP of the AST identified the need to foster the safe expansion of LDLT across the US. To accomplish this important objective, these groups outlined goals to a) collaboratively bring together US and International leaders in LDLT to exchange experience and knowledge, b) to identify barriers and data gaps to broader expansion of LDLT in the US, and c) to develop consensus recommendations to address barriers and data gaps to promote the safe expansion of LDLT. Workgroups focused on selected domains encompassing the entire process of LDLT were created. Consensus conference participants were selected, invited, and distributed among the workgroups. Consensus conference participants were a diverse cohort, representing numerous stakeholders

relevant to LDLT. The consensus conference was held virtually on October 18–19, 2021. A modified Delphi approach was utilized as the consensus methodology. Complete information including the list of consensus conference workgroup domains, the process regarding consensus conference participant selection, development and refinement of consensus statements, and modified Delphi methodology, are reported elsewhere.¹⁹ As part of the process, literature searches were developed with terms related to living liver donor and candidate selection and engagement, performed by two librarians with expertise in systematic reviews. The literature searches were distributed to workgroup members for review and selection. Additional details regarding the systematic review and search syntax are included in Supplemental Files Table A.

To determine consensus, a modified Delphi approach was implemented including both the virtual consensus meeting, where consensus statements were discussed and refined for content and clarity, and two separate polling sessions (approximately 2 months apart). Polling responses were based upon a nine-point scale, barrier statement response options ranged from 1 = Unimportant to 9 = Very Important. Mitigation strategies were rated for both impact and feasibility, with response options ranging from 1 = Not Impactful or Not Feasible to 9 = Very Impactful or Very Feasible. Consistent with Delphi polling approaches, the center point across all response options (or a rating of 5) permitted for a response of “Uncertain.” For the definition of consensus, minimum consensus participant response rate to each poll was set at 70% and minimum consensus across statements was again conservatively set at no greater than 30% of respondents’ rankings outside of the central interquartile range (IQR). Analyses of polling responses were simple descriptives using IBM SPSS V.27 software.

3 | CONSENSUS FINDINGS

Participation across polling sessions related to our workgroup exceeded minimum participation thresholds. Complete consensus statements regarding barriers to expansion of LDLT and impact and feasibility scores for candidate selection and engagement are reported in Table 1 and donor selection and engagement statements are reported in Table 2. All barriers are listed in order of rated importance as viewed by the conference participants, based upon mean scores. Most of the barriers were ranked as highly important, but responses across impact and feasibility of strategies to address barriers varied. Across both candidates and donors, barriers to selection and engagement for LDLT pertained to 1) awareness, acceptance, and engagement across patients (potential candidate and donors), providers, and institutions, 2) data gaps and lack of standardization in candidate and donor selection, and 3) data gaps regarding post-living liver donation outcomes and resource needs. As indicated by Figure 1, there is overlap and interactions across these domains and, as such, there is also overlap among strategies aimed at addressing barriers which include education, research, training, and investments in infrastructure. All of these factors operate within the broader culture of LDLT throughout the US.

3.1 | Awareness, acceptance, and engagement across candidates, donors, providers, and institutions

Many of the identified barriers focused on or addressed domains related to a culture of reluctance or even resistance toward LDLT across providers, both referring and transplant providers, as well as potential candidates and institutions. Discussion during the meeting emphasized that broader clinician engagement and awareness of the benefits of LDLT to the transplant candidate is paramount and needs to occur before patients can be appropriately engaged. In essence, the clinical culture surrounding LDLT (Figure 1) needs to change in order for LDLT to safely grow throughout the US.

For candidates, consensus attendees rated “Gaps in the knowledge on benefits, risks and timing of LDLT and the risks/benefits to the living liver donor among transplant physicians and referring providers” as the overall highest barrier to waitlist candidate access to LDLT (Table 1, barrier #1). Similarly, the highest rated pediatric barrier pointed out that LDLT is not always considered a first option for the many eligible pediatric liver candidates (Table 1, barrier #3). Additional candidate barrier statements with similar themes and rated important touch upon institutional commitment (Table 1, barrier #4), concerns regarding or lack of agreement on risks relative to benefit (Table 1, barriers #7 and #8), and lack of waitlist candidate acceptances of LDLT as a viable option (Table 1, barrier #9). Based upon conference discussion and the literature reviewed, across both adult and pediatric populations,^{20–22} there was agreement that LDLT is beneficial for the recipient when balanced against the risk of the donor. Developing education for referring and transplant providers on risks and benefits for the candidates and living donors including appropriate timing of referral and candidate selection were considered both highly impactful and feasible strategies. Goals of clinician education should include benefits of LDLT, risk assessment, and timing of transplantation for successful outcomes. The AST Living Liver Donor Provider Tool Kit²³ is an example of a publicly available resource that can facilitate educational initiatives about LDLT to providers.

As stated above, consensus attendees verbalized engaging providers and changing the clinical culture around LDLT as the first step to engaging the broader patient community. While several candidate-level engagement barriers were identified, the main concern in engaging donors was to ensure equitable access across racial minority groups (Table 2, barrier #2). While there are few studies examining racial disparities in access to LDLT, the existing data suggests proportion of LDLT rates are lower among Hispanic and Black populations compared to Whites.^{24,25} Consensus conference participants noted that transplant center-level efforts towards engaging minority and underserved communities had the potential to be highly impactful and feasible. Emphasis was on collection of center-level data to inform programmatic work to address center specific disparities in access to LDLT and on diversification of hiring practices of transplant healthcare providers to increase racially/ethnically concordant patient-physician dyads. Though consensus was not achieved on feasibility of creating a targeted racial/ethnic educational program to encourage more

TABLE 1 Candidate selection and engagement (n = 46, 90.2% response rate).

# Priority Importance of Barrier • Strategy(ies)		Consensus Responses Mean (SD); Median (IQR)	
#1	Gaps in the knowledge on benefits, risks and timing of LDLT and the risks/benefits to the living liver donor among transplant physicians and referring providers.	<i>Importance:</i>	8.39 (.93); 9 (8, 9)
	• Develop education for referring and transplant providers on risks and benefits for the candidates and living donors including appropriate timing of referral and candidate selection.	<i>Impact</i> <i>Feasibility:</i>	8.30 (.96); 9 (8, 9) 8.17 (.90); 8 (7, 9)
#2	Lack of uniform consideration of the benefit of LDLT in select patients with low MELD-Na among transplant and referring providers. For example, many transplant providers are unaware that low MELD-Na (<15) patients with sarcopenia, frailty, decompensating events, infections, or women benefit from LDLT, compared to waiting for rise in MELD-Na or DDLT.	<i>Importance:</i>	8.19 (.87); 8 (8, 9)
	• MELD-Na alone should not be used to determine candidacy for LDLT. Additional factors influencing wait list morbidity, mortality and QOL/PRO should be considered in LDLT decision making.	<i>Impact:</i> <i>Feasibility:</i>	7.77 (1.31); 8 (7, 9) 7.49 (1.41); 8 (7, 8) ^a
	• Continued research is needed to identify patients with low MELD-Na who are at highest risk of wait list mortality and will benefit from early LDLT.	<i>Impact:</i> <i>Feasibility:</i>	7.52 (1.47); 8 (7, 9) 7.59 (1.29); 8 (7, 9)
#3	LDLT in the United States and some other regions is not always considered a first choice for many pediatric patients eligible for liver transplant.	<i>Importance:</i>	8.02 (1.05); 8 (7, 9)
	• Adopting LDLT as the preferred approach for appropriate pediatric liver transplantation will increase the rates of living donor liver transplant.	<i>Impact:</i> <i>Feasibility:</i>	8.21 (.93); 8 (8, 9) 7.51 (1.30); 8 (7, 9)
	• Use of technology for education, evaluation, advance imaging, together with adopting non directed altruistic donation with a safe MIS approach can transform traditional programs into a state-of-the art system and address existing disparities.	<i>Impact:</i> <i>Feasibility:</i>	7.60 (1.50); 8 (7, 9) 6.91 (1.53); 7 (6, 8) ^a
#4	Limited institutional commitment to enable the liver transplant program to develop optimal living donor liver transplantation practices to benefit a large proportion of candidates on the waiting list.	<i>Importance:</i>	8.02 (1.03); 8 (8, 9)
	• Develop a process for bidirectional communication between institution leadership and the liver transplant program for enhanced resources for a successful LDLT program including resources for community outreach and education.	<i>Impact:</i> <i>Feasibility:</i>	8.09 (.92); 8 (8, 9) 7.00 (1.55); 7 (6, 8) ^a
	• Build a dedicated LDLT team with LDLT surgeon, coordinator, medical director, and LDLT advocate, mental health, consultation services, and other system-level resources.	<i>Impact:</i> <i>Feasibility:</i>	8.33 (.85); 8 (8, 9) 7.09 (1.61); 7 (6, 8.75)
#5	In critically ill patients, centers need sufficient surgical/medical experience to provide optimal pre- and post-surgical management.	<i>Importance:</i>	7.79 (1.55); 8 (7, 9)
	• Programs will need resources to ensure ongoing clinical care and follow-up.	<i>Impact:</i> <i>Feasibility:</i>	7.43 (1.65); 8 (7, 9) 6.53 (1.81); 7 (5, 8)
	• Experienced centers and national organizations can teach/proctor others.	<i>Impact:</i> <i>Feasibility:</i>	7.04 (1.56); 7 (6, 8) ^a 6.34 (1.66); 7 (5, 8)
	• If there were adequate resources, programs may be able to overcome the psychological barriers to adopt LDLT.	<i>Impact:</i> <i>Feasibility:</i>	6.91 (1.79); 7 (6, 9) 6.36 (1.88); 6 (6, 7) ^a
	• High MELD patients may require LDLT to be performed 52 weeks a year.	<i>Impact:</i> <i>Feasibility:</i>	7.21 (1.37); 7 (7, 8) ^a 5.74 (1.88); 6 (4, 7) ^a
#6	Accurately knowing which patients with extended HCC criteria (without vascular invasion and extrahepatic mets), based on disease burden and tumor biology, will benefit from a LDLT from a survival perspective.	<i>Importance:</i>	7.54 (1.19); 8 (7, 8) ^a
	• Further data needed (multicenter data) for better patient selection.	<i>Impact:</i> <i>Feasibility:</i>	7.26 (1.51); 7 (6, 9) 7.09 (1.40); 7 (6, 8) ^a
	• Achieve response to treatment (downstage with local-regional therapy to AFP <500 ng/mL pre-LDLT with an observation period of at least 3 months pre-LDLT).	<i>Impact:</i> <i>Feasibility:</i>	7.20 (1.53); 7 (7, 8) ^a 7.20 (1.36); 7 (6, 8)

(Continues)

TABLE 1 (Continued)

# Priority Importance of Barrier • Strategy(ies)		Consensus Responses Mean (SD); Median (IQR)
#7	Pediatric transplant clinicians lack agreement on the benefits of pediatric LDLT.	<i>Importance:</i> 7.53 (1.52); 8 (6, 9)
	• Educational campaigns on the benefits of LDLT for the broader pediatric healthcare community and transplant professionals on the outcomes' superiority are needed.	<i>Impact:</i> 7.81 (1.19); 8 (7, 9) <i>Feasibility:</i> 7.62 (1.17); 8 (7, 9)
	• Education for patient communities on the safety and availability of living liver donation, and multicenter listing through advocacy groups and national organizations. Acceptance of LDLT first approaches will require sustained effort, education, and culture change. Partnerships between pediatric & adult centers to improve provider and patient awareness and optimize LDLT access and outcomes for all should be encouraged.	<i>Impact:</i> 7.79 (1.08); 8 (7, 9) <i>Feasibility:</i> 7.40 (1.31); 8 (7, 8) ^a
	• Pediatric centers with limited hepatic donor experience should partner with experienced adult centers to increase pediatric access to and improve pediatric outcomes with LDLT.	<i>Impact:</i> 7.79 (1.30); 8 (7, 9) <i>Feasibility:</i> 6.63 (1.90); 7 (5, 75, 8) ^a
#8	Ethical concerns regarding donors' risks and recipients' benefit limits the possibility of LDLT in patients with relative poor/unknown prognosis (non-resectable colorectal liver metastases and intrahepatic cholangiocarcinoma).	<i>Importance:</i> 7.52 (1.53); 8 (7, 9)
	• Double equipoise should prevail and assess with comprehensive donor evaluation and informed consent when considering LDLT in these populations to ensure both minimal risk to donors and maximal possible survival to the recipient.	<i>Impact:</i> 7.30 (1.50); 8 (6, 75, 8) ^a <i>Feasibility:</i> 6.91 (1.42); 7 (6, 8)
#9	There is a low level of acceptance of LDLT among candidates on the liver transplant waiting list.	<i>Importance:</i> 7.40 (1.64); 8 (7, 9)
	• Develop fact-based educational materials on risks and benefits of LDLT for transplant candidates.	<i>Impact:</i> 8.32 (.87); 9 (8, 9) <i>Feasibility:</i> 8.26 (.95); 9 (8, 9)
	• Utilize the AST LDLT tool kit to educate the transplant candidates about the risks and benefits to the living liver donor.	<i>Impact:</i> 8.03 (.88); 8 (7, 9) <i>Feasibility:</i> 8.30 (.81); 8.5 (8, 9)
	• Develop outreach programs, across transplant and community settings, for patients, families, and additional supports on the benefits of living donor transplantation and dispelling myths and misconceptions about LDLT and the stigma associated with certain liver diseases.	<i>Impact:</i> 8.13 (.96); 8 (7, 9) <i>Feasibility:</i> 7.43 (1.34); 8 (6, 75, 9)
	• Adapt programs utilized in living donor kidney transplantation (living donor champion/coaching/mentorship programs) to help liver transplant candidates find potential living donors.	<i>Impact:</i> 8.07 (1.02); 8 (7, 9) <i>Feasibility:</i> 7.84 (1.01); 8 (7, 9)
	• Evaluate new and existing outreach and educational programs to determine their effectiveness.	<i>Impact:</i> 8.07 (1.03); 8 (7, 9) <i>Feasibility:</i> 7.48 (1.38); 8 (7, 9)
#10	Lack of data on LDLT for non-resectable colorectal liver metastases and intrahepatic cholangiocarcinoma outcomes to justify exposure of a healthy donor to a major surgery.	<i>Importance:</i> 7.09 (1.53); 7 (6, 8.5) ^a
	• Experienced centers under strict protocols should enroll patients in prospective trials and/or formal protocols with continued review of outcomes and monitoring with a registry.	<i>Impact:</i> 7.24 (1.70); 8 (6, 9) <i>Feasibility:</i> 6.43 (1.68); 7 (5, 75, 8)
#11	Common belief that overall survival rate of a recipient with HCC beyond Milan criteria does not justify the risks for a living donor.	<i>Importance:</i> 7.00 (1.62); 7 (6, 8) ^a
	• Survival benefit is still advantageous for these patients. A minimum acceptable recipient overall survival at 5-years post LDLT with generally comparable survival benefit to deceased donor (if available) to balance survival benefit/donor risk. We need to make sure this is risk adjusted in our US models. We need alternate methods to evaluate LDLT vs deceased donor outcomes in this sub-population in the US.	<i>Impact:</i> 7.38 (1.27); 8 (7, 8) ^a <i>Feasibility:</i> 6.85 (1.46); 7 (6, 8) ^a
#12	Patients with low MELD-Na and cirrhosis are not aware that LDLT provides better 3-year survival than waiting for a DDLT, especially those with a decompensating event.	<i>Importance:</i> 6.96 (.91); 7 (6, 8)
	• Better educational efforts to inform listed patients and families of survival benefits of early LDLT compared to waiting for DDLT are needed.	<i>Impact:</i> 8.19 (.92); 8 (8, 9) <i>Feasibility:</i> 8.28 (.97); 9 (8, 9)

(Continues)

TABLE 1 (Continued)

# Priority Importance of Barrier • Strategy(ies)	Consensus Responses Mean (SD); Median (IQR)	
<ul style="list-style-type: none"> Improved comparative effectiveness data between LDLT and waiting for DDLT will better inform patient decisions. Centers that do not perform LDLT should make patients aware of the potential benefits of LDLT and the potential for multiple listing. 	<i>Impact:</i>	8.00 (1.02); 8 (7, 9)
	<i>Feasibility:</i>	7.63 (1.12); 8 (7, 9)
<ul style="list-style-type: none"> Centers that do not perform LDLT should make patients aware of the potential benefits of LDLT and the potential for multiple listing. 	<i>Impact:</i>	8.00 (1.21); 8 (7, 9)
	<i>Feasibility:</i>	6.60 (1.85); 7 (5, 8)
#13 Payors may not cover a liver transplant for a patient with a MELD-Na <15.	<i>Importance:</i>	6.96 (2.24); 8 (5, 9)
<ul style="list-style-type: none"> Transplant Societies and Advocacy Groups need to work with payors to improve payor reimbursement for appropriate candidates with low MELD-Na. 	<i>Impact:</i>	7.45 (1.68); 8 (6, 9)
	<i>Feasibility:</i>	7.15 (1.52); 7.5 (6, 8.25) ^a
<ul style="list-style-type: none"> Transplant Societies and Advocacy Groups should support improved data collection on costs of care in patients with low MELD and transplant to understand overall cost savings in early transplant. 	<i>Impact:</i>	7.55 (1.50); 8 (7, 9)
	<i>Feasibility:</i>	7.11 (1.58); 7 (6, 8) ^a
#14 For patients with acute liver failure/severe disease, inadequate donor liver mass for given recipient is a limiting factor and time is wasted.	<i>Importance:</i>	6.93 (1.64); 7 (6, 8) ^a
<ul style="list-style-type: none"> In urgent situations, perform early donor imaging to avoid wasting program resources on entire evaluation for donor with unacceptable anatomy. 	<i>Impact:</i>	7.72 (1.46); 8 (7, 9)
	<i>Feasibility:</i>	7.54 (1.96); 8 (7, 9)
<ul style="list-style-type: none"> Rapid processing to accommodate additional donor candidates until suitable donor is found as timing to transplant improves outcomes. 	<i>Impact:</i>	7.41 (1.42); 8 (7, 8) ^a
	<i>Feasibility:</i>	6.80 (1.82); 7 (6, 8) ^a
<ul style="list-style-type: none"> In the high acuity setting, explore/test feasibility of interventions to engage families and additional supports to identify potential living donors. 	<i>Impact:</i>	7.26 (1.60); 7 (6.75, 8.25) ^a
	<i>Feasibility:</i>	6.61 (1.78); 7 (6, 8) ^a
#15 For patients with acute liver failure/severe disease, centers need to be capable of performing a rapid donor evaluation and informed consent process and have operative room capacity for LDLT in parallel with deceased donor transplants.	<i>Importance:</i>	6.79 (1.91); 7 (6, 8) ^a
<ul style="list-style-type: none"> Programs that perform LDLT for ALF/severe disease need institutional commitment/resources to perform LD evaluations 7 days/week - including experienced multidisciplinary teams, diagnostic testing resources and operating room resources. 	<i>Impact:</i>	6.96 (1.96); 8 (6, 8) ^a
	<i>Feasibility:</i>	6.23 (1.67); 6 (5, 8)
<ul style="list-style-type: none"> Experienced centers and national organizations can teach/proctor others. 	<i>Impact:</i>	6.87 (1.95); 7 (6, 8) ^a
	<i>Feasibility:</i>	6.49 (1.72); 7 (6, 8) ^a
<ul style="list-style-type: none"> Develop an alternative template for rapid living donor liver transplant evaluation. 	<i>Impact:</i>	6.98 (1.71); 7 (6, 8) ^a
	<i>Feasibility:</i>	7.30 (1.63); 8 (7, 8) ^a
<ul style="list-style-type: none"> Informing the living liver donor of the purpose of this alternative evaluation weighing the risks vs. benefits. 	<i>Impact:</i>	7.09 (1.77); 7 (6, 8) ^a
	<i>Feasibility:</i>	7.23 (1.59); 8 (6, 8)

Barriers ordered from highest to lowest rated priority. Response options rated from 9 = Very Important, Very Impactful, or Very Feasible to 1 = Unimportant, Not Impactful, or Not Feasible.

^aIndicates consensus was not met across responses, based upon above outlined consensus methods.

minority living donors to come forward, this possibly reflects limited resource allocation for community-based outreach as well as the lack of data to guide such a program. Further research is needed to identify systemic barriers to LDLT for diverse populations.

Much of the data focused on fostering living donation currently comes from the kidney literature, for example Barnieh et al.²⁶ and Hunt et al.,²⁷ although there have been reports of successful translation to liver transplant candidates and living liver donors.²⁸ Key concepts from the living donor kidney transplant literature include education of the transplant candidate and support system on multiple occasions, physician involvement with reinforcement from all transplant team members, use of social media, and peer support.^{26,27} As some providers may be hesitant to recommend LDLT for a potential candidate, providing comprehensive education on potential benefits and risks is not only essential for informed consent but also to address possible misconceptions, provide information on identifying potential

living liver donors, and strategies to engage potential donors once identified. While much can be learned from the living kidney donor literature, there are unique considerations for liver populations that will likely require targeted education and intervention. In the interim, strategies rated as highly impactful and feasible included developing fact-based educational materials on risks and benefit of LDLT for transplant candidates. Broader development and implementation of outreach programs were also identified as a needed strategy. These were recommended to focus not only on benefits, but also dispelling myths and misconceptions about LDLT, and addressing the stigma associated with certain liver diseases. While developing and implementing outreach programs met consensus agreement for impact, feasibility was somewhat lower, again likely reflecting needed resources to accomplish community outreach programs.

The broader engagement of institutions is essential for allocation of resources and required infrastructure. Two highly rated barriers

TABLE 2 Donor selection and engagement (n = 46, 90.2% response rate)

# Priority Importance of Barrier • Strategy(ies)	Consensus Responses Mean (SD); Median (IQR)			
<p>#1 Living liver donors incur significant out-of-pocket costs that serve as an important barrier to living donation, particularly in minority communities, where incomes are significantly lower compared to non-Hispanic White populations.</p> <ul style="list-style-type: none"> • Transplant centers should require collection of income information and household size in potential donors and transplant candidates to facilitate filing of applications to the National Living Donor Assistance Center, the only current national resource that addresses financial barriers for living donors. • Centers should review NLDAC application processes to ensure work-flow is easy and takes the burden away from vulnerable recipients and donor candidates. • Greater attention to pursuing both local and national policies to protect living donors • Current paired exchange programs for kidney donors offer protections that should be considered for living liver donors. 	<p><i>Importance:</i> 8.46 (1.05); 9 (8, 9)</p> <p><i>Impact:</i> 7.85 (1.26); 8 (7, 9)</p> <p><i>Feasibility:</i> 7.39 (1.32); 8 (6.75, 8.25)^a</p> <p><i>Impact:</i> 8.15 (.97); 8 (7.75, 9)</p> <p><i>Feasibility:</i> 7.83 (1.20); 8 (7, 9)</p> <p><i>Impact:</i> 8.11 (1.16); 8.5 (7.75, 9)</p> <p><i>Feasibility:</i> 7.41 (1.36); 8 (7, 8.25)^a</p> <p><i>Impact:</i> 8.00 (1.37); 8 (7, 9)</p> <p><i>Feasibility:</i> 7.07 (1.68); 7 (6, 8)^a</p>			
	<p>#2 African Americans, Hispanics and other minority groups undergo LDLT at lower rates when accounting for severity of disease, type of disease, and residence. Among the most common reasons for lower rates of LDLT are lower inquiries about living donation by potential donors in family/social network, and opting out at earlier steps in the process, which are actionable by centers.</p> <ul style="list-style-type: none"> • Encourage targeted education programs to minority communities to encourage more potential donors to come forward. Transplant centers should utilize, educate and assess known strategies that improve access for minority patients. • Centers should continuously engage with their own data on donor recruitment to inform their own programmatic initiatives to address center-level barriers to reduce disparities in access to LDLT. • Transplant centers should actively foster racial/ethnic diversity in hiring practices which will increase culturally-concordant patient-provider dyads to emerge more frequently, which are associated with improved health outcomes. 	<p><i>Importance:</i> 8.09 (1.07); 8 (7, 9)</p> <p><i>Impact:</i> 8.04 (.97); 8 (7.75, 9)</p> <p><i>Feasibility:</i> 7.46 (1.35); 8 (7, 8.25)^a</p> <p><i>Impact:</i> 8.09 (1.01); 8 (8, 9)</p> <p><i>Feasibility:</i> 7.63 (1.37); 8 (7, 9)</p> <p><i>Impact:</i> 7.78 (1.11); 8 (7, 9)</p> <p><i>Feasibility:</i> 7.39 (1.47); 7.5 (6, 9)</p>		
		<p>#3 Obesity, metabolic syndrome, and non-alcoholic fatty liver disease are highly prevalent in the U.S. population and have limited the pool of living donor candidates.</p> <ul style="list-style-type: none"> • BMI is not an adequate independent predictor of hepatic steatosis and NASH alone. Risk stratify potential living liver donors with attention to visceral fat distribution, risk factors for metabolic syndrome, quantification of hepatic steatosis, and also fibrosis as appropriate. • Exclude donors with diabetes, active steatohepatitis, and/or hepatic fibrosis. Consider donors with obesity and/or risk factors for metabolic syndrome if resources allow for utilization of metabolic health and weight loss programs for risk mitigation. • Advocate for resources to use to explore expansion of donor metabolic health and weight loss programs and to support formalized post-donation care. 	<p><i>Importance:</i> 8.02 (1.13); 8 (8, 9)</p> <p><i>Impact:</i> 7.59 (1.17); 8 (7, 9)</p> <p><i>Feasibility:</i> 6.98 (1.87); 7 (6, 8)^a</p> <p><i>Impact:</i> 7.61 (1.32); 8 (7, 8.25)^a</p> <p><i>Feasibility:</i> 7.21 (1.69); 7 (6, 8)</p> <p><i>Impact:</i> 7.78 (1.07); 8 (7, 9)</p> <p><i>Feasibility:</i> 6.57 (1.67); 7 (6, 8)</p>	
			<p>#4 There are few guidelines regarding psychosocial donor contraindications and rule-outs.</p> <ul style="list-style-type: none"> • Prioritize research and scholarship into psychosocial risks, outcomes, and team processes to identify psychosocial factors that are and are not associated with poor donor outcomes. • Prioritize research and scholarship into psychosocial risks, outcomes, and team processes to help standardize the minimum psychosocial evaluation and clinical decision-making processes between centers. 	<p><i>Importance:</i> 7.74 (1.34); 8 (7, 9)</p> <p><i>Impact:</i> 7.87 (1.36); 8 (7, 9)</p> <p><i>Feasibility:</i> 7.13 (1.56); 8 (6, 8)^a</p> <p><i>Impact:</i> 7.98 (1.16); 8 (7.75, 9)</p> <p><i>Feasibility:</i> 7.07 (1.65); 7.5 (6, 8)^a</p>
				<p>#5 Discussions to expand donor acceptance rates will rely on a better understanding of center-variable donor evaluation processes including testing and reasons for rule out, then follow donors both approved and declined overtime for short-term and long-term outcomes to inform attributable risk tolerance discussions. Strategies for routine follow up of the donor evaluation process, short-term and long-term living liver donor outcomes is needed.</p>

(Continues)

TABLE 2 (Continued)

# Priority Importance of Barrier • Strategy(ies)	Consensus Responses Mean (SD); Median (IQR)	
<ul style="list-style-type: none"> A living donor registry is needed to incorporate the components of the donor evaluation including testing, reasons for rule out and then to follow donors both approved and declined overtime for short-term and long-term outcomes. Any registry would need to overcome hurdles such as the burden of data entry and finances through electronic data transfer and funding. Likewise, any registry would need to make its data available to be obtained deidentified. National societies should endorse data collection by having an expectation of minimal data sharing. High volume centers should come together to combine and publish their data on reasons donors are declined for medical, anatomic and psychosocial reasons. Patients should be educated that different centers may have different criteria for donor approval. Donors with incidental findings need to be directed to appropriate follow up. 	<i>Impact:</i> 7.32 (1.84); 8 (6, 9) <i>Feasibility:</i> 6.54 (1.79); 7 (5, 8) ^a	
<ul style="list-style-type: none"> Lack of long-term follow up data on donors treated in metabolic health and weight loss programs limit the ability to counsel donors regarding long term risk and health outcomes. A multicenter prospective study to collect long term follow up data in this subpopulation of donors. 	<i>Impact:</i> 7.30 (1.92); 8 (6, 9) <i>Feasibility:</i> 7.07 (1.91); 7 (6, 9) <i>Impact:</i> 7.63 (1.50); 8 (7, 9) <i>Feasibility:</i> 6.80 (1.71); 7 (6.75, 9) ^a <i>Impact:</i> 7.50 (1.56); 8 (6.75, 9) <i>Feasibility:</i> 7.35 (1.58); 7.5 (6, 9) <i>Impact:</i> 7.20 (2.18); 8 (6, 9) <i>Feasibility:</i> 7.67 (1.38); 8 (7, 9)	
#6	<ul style="list-style-type: none"> Lack of long-term follow up data on donors treated in metabolic health and weight loss programs limit the ability to counsel donors regarding long term risk and health outcomes. A multicenter prospective study to collect long term follow up data in this subpopulation of donors. 	<i>Importance:</i> 7.63 (1.37); 8 (6.75, 9) <i>Impact:</i> 7.57 (1.47); 8 (7, 9) <i>Feasibility:</i> 6.50 (1.75); 7 (5, 8)
#7	<p>The full spectrum of donor post-donation psychosocial gains and complications is unclear.</p> <ul style="list-style-type: none"> Increase prospective post-donation psychosocial data collection, both qualitative and quantitative. Develop a standardized set of existing psychometric instruments that centers can employ for donor follow-up. Consider psychosocial follow-up as equivalent in importance and frequency to donor medical follow-up. 	<i>Importance:</i> 7.41 (1.51); 8 (6.75, 9) <i>Impact:</i> 7.37 (1.45); 8 (7, 8) ^a <i>Feasibility:</i> 6.33 (1.71); 8 (5, 7) ^a <i>Impact:</i> 7.33 (1.55); 8 (7, 8) ^a <i>Feasibility:</i> 6.72 (1.67); 7 (6, 8) <i>Impact:</i> 7.35 (1.59); 8 (7, 8) ^a <i>Feasibility:</i> 6.64 (1.67); 7 (5, 8)
#8	<p>Hypercoagulable testing is widely variable between centers and the significance of the results are not always clear. There is no consensus about the optimal screening strategy for donors.</p> <ul style="list-style-type: none"> Consensus on donor risk tolerance and testing strategy is needed. High volume centers should come together to combine and publish their data. Collaboration with hematology colleagues should be encouraged. 	<i>Importance:</i> 7.33 (1.65); 8 (6.75, 9) <i>Impact:</i> 7.13 (1.71); 7 (6, 9) <i>Feasibility:</i> 6.91 (1.67); 7 (6, 8) ^a
#9	<p>We have too few psychosocial clinicians with time and/or specialization to evaluate and follow the growing and increasingly complex donor pool.</p> <ul style="list-style-type: none"> Increase outreach to improve psychosocial clinician awareness, training, and recruitment. Increase institutional support to maximize chances of durable implementation. 	<i>Importance:</i> 7.33 (1.93); 8 (6, 9) <i>Impact:</i> 7.13 (1.73); 8 (6, 8) ^a <i>Feasibility:</i> 6.57 (1.53); 7 (6, 8) <i>Impact:</i> 7.58 (1.64); 8 (6, 9) <i>Feasibility:</i> 6.46 (1.57); 7 (6, 8)
#10	<p>The psychosocial impact of declined donor evaluations is poorly understood.</p> <ul style="list-style-type: none"> Routine tracking of declined donors and evaluation of related clinical communication processes. Research outcomes for declined donors in comparison to other donor populations. Draw upon the resources of the Living Donor Collective to follow-up with the declined donor population. 	<i>Importance:</i> 7.26 (1.77); 8 (6, 9) <i>Impact:</i> 6.78 (1.97); 7 (6, 8) ^a <i>Feasibility:</i> 5.61 (1.78); 6 (4, 7) <i>Impact:</i> 6.53 (2.00); 7 (6, 8) ^a <i>Feasibility:</i> 5.67 (1.84); 6 (4.75, 7) ^a <i>Impact:</i> 6.50 (2.12); 7 (5, 8) ^a <i>Feasibility:</i> 6.26 (2.09); 7 (5, 8) ^a
#11	<p>The full spectrum of donor post-donation psychosocial gains and complications is unclear.</p> <ul style="list-style-type: none"> Increase prospective post-donation psychosocial data collection, both qualitative and quantitative. Develop a standardized set of existing psychometric instruments that centers can employ for donor follow-up. 	<i>Importance:</i> 7.19 (1.47); 7 (6, 8) ^a <i>Impact:</i> 7.37 (1.45); 8 (7, 8) ^a <i>Feasibility:</i> 6.33 (1.71); 7 (5, 7) ^a <i>Impact:</i> 7.33 (1.55); 8 (7, 8) ^a <i>Feasibility:</i> 6.72 (1.67); 7 (6, 8)

(Continues)

TABLE 2 (Continued)

# Priority Importance of Barrier • Strategy(ies)		Consensus Responses Mean (SD); Median (IQR)
• Consider psychosocial follow-up as equivalent in importance and frequency to donor medical follow-up.	<i>Impact:</i>	7.35 (1.59); 8 (7, 8) ^a
	<i>Feasibility:</i>	6.64 (1.67); 7 (5.5, 8)
#12 There is limited knowledge of the impact on transplantation outcomes and donor risk when first degree relatives donate to transplant candidates with NASH.	<i>Importance:</i>	7.04 (1.65); 7 (6, 8.25) ^a
• Advocacy for funding formal research study with incorporation of novel genetic testing is warranted to understand risk and outcomes for donors with obesity, metabolic risk or hepatic steatosis.	<i>Impact:</i>	6.96 (1.57); 7 (5.75, 8) ^a
	<i>Feasibility:</i>	6.21 (1.64); 6.5 (5, 7) ^a
#13 Because of the extensive testing each donor undergoes, incidental findings are to be expected. Some of these incidental findings may be of unclear significance.	<i>Importance:</i>	7.02 (1.77); 7 (6, 8) ^a
• Suggest attention to quantifying outcome through a central data resource, this may also include incidental findings in the deceased donor population as well.	<i>Impact:</i>	6.67 (1.74); 7 (5.75, 8) ^a
	<i>Feasibility:</i>	6.09 (1.80); 6 (5, 7) ^a
#14 Psychosocial integration into medical, surgical clinical workflows and research may be inadequate for living donation expansion.	<i>Importance:</i>	6.93 (1.77); 7 (5.75, 8) ^a
• Expand interprofessional team culture and collaboration.	<i>Impact:</i>	7.23 (1.51); 7 (7, 8) ^a
	<i>Feasibility:</i>	6.80 (1.56); 7 (6, 8) ^a
• Educate transplant team members and disseminate best practices regarding psychosocial assessment.	<i>Impact:</i>	7.30 (1.52); 7 (7, 9)
	<i>Feasibility:</i>	7.13 (1.58); 7 (6, 8) ^a
• Engage in implementation research and evaluate how to integrate psychosocial workflows in clinical practice.	<i>Impact:</i>	7.00 (1.66); 7 (6, 8) ^a
	<i>Feasibility:</i>	6.59 (1.65); 7 (6, 7) ^a
#15 Lack of standardization in the use of donors heterozygous for genetic and metabolic diseases for LDLT is a barrier to increasing LDLT utilization in children.	<i>Importance:</i>	6.89 (1.64); 7 (5, 8)
• Develop evidence-based, standardized criteria for use of these donors through multi center collaboration.	<i>Impact:</i>	5.89 (2.38); 6 (4, 8.75) ^a
	<i>Feasibility:</i>	5.39 (2.17); 5 (4, 7) ^a
• AST Living Donor Toolkit chapter provides recommendations relevant to some of the genetic and metabolic diseases that children undergo LT to treat: Donors for Recipients with Hereditary Liver Disease.	<i>Impact:</i>	6.05 (2.22); 6 (4, 8) ^a
	<i>Feasibility:</i>	6.11 (2.38); 6.5 (4, 8) ^a
#16 The incidence of AAT carriers is high but there is no consensus about the use of donors with an a1AT allele likely due to a paucity of knowledge about risk of future liver disease in these carriers.	<i>Importance:</i>	6.85 (1.38); 7 (6, 8) ^a
• AAT carriers may be used as donors with caution. These patients have an incremental increase and lifetime risk of cirrhosis but living liver donation is safe in the short term and has minimal long-term risk. Counseling about the risk of a "second hit" to increase risk of liver disease for these donors and recipients should be considered.	<i>Impact:</i>	6.64 (1.40); 7 (5, 8)
	<i>Feasibility:</i>	6.53 (1.47); 7 (5, 8)
#17 Positive iron testing found incidentally in a donor including but not limited to elevated transferrin and iron detected by MRI should prompt evaluation for hereditary hemochromatosis which would be contraindication for liver donation (supported by C282Y homozygosity and intracellular iron deposition in hepatocytes). However, hemosiderosis in Kupffer cells is more suggestive of secondary iron overload and there is evidence that some degree of hemosiderosis is safe for donation.	<i>Importance:</i>	6.43 (1.59); 6 (5, 8)
• The presence of iron does not need to result in automatic donor decline. There is some evidence that donors with secondary hemosiderosis may safely donate. Iron overload should be assessed on a case-by-case basis.	<i>Impact:</i>	6.57 (1.42); 7 (5, 8)
	<i>Feasibility:</i>	6.69 (1.49); 7 (5.5, 8)

Barriers ordered from highest to lowest rated priority. Response options rated from 9 = Very Important, Very Impactful, or Very Feasible to 1 = Unimportant, Not Impactful, or Not Feasible.

^aIndicates consensus was not met across responses, based upon above outlined consensus methods.

(Table 1, barriers #4 and #5) focused on institutional commitment, resources, and infrastructure to support LDLT. For barrier #4 on limited institutional commitment, the strategy "Build a dedicated LDLT team ..." was rated the highest for overall impact across all strategies listed herein. While feasibility for this recommended strategy was

somewhat lower, both impact and feasibility of this statement met consensus. Efforts to increase LDLT volume require sufficient programmatic and financial resources to support all relevant components of the program, ultimately ensuring responsible increases in the number of LDLTs with positive outcomes. These include advanced medical

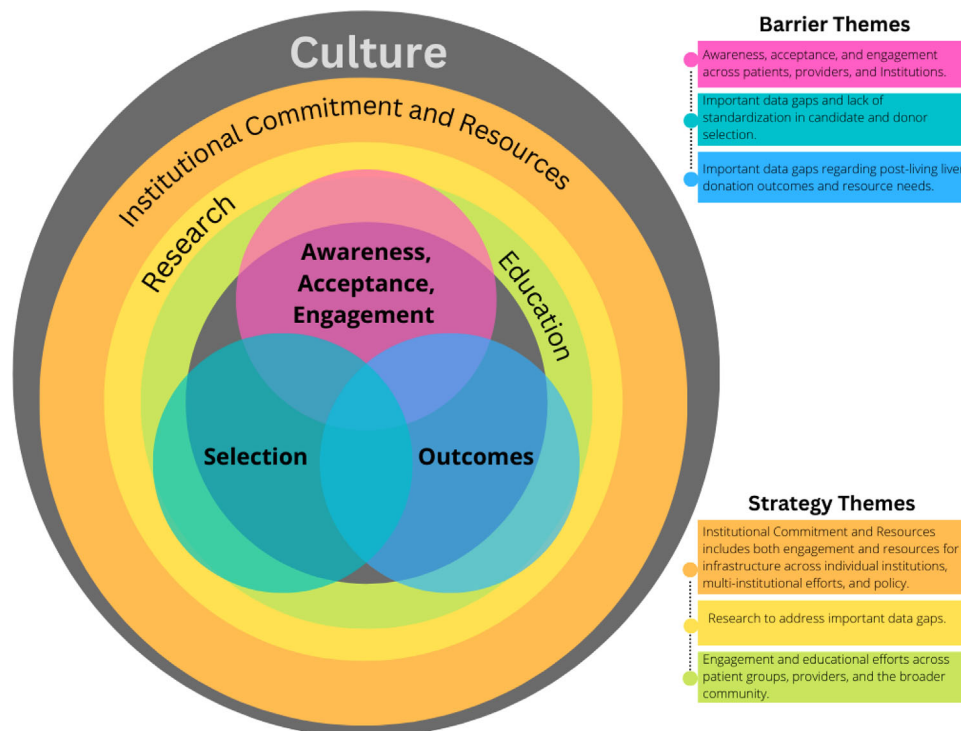


FIGURE 1 Themes of barriers and strategies in candidate and donor selection/engagement for LDLT.

expertise in living donation for appropriate candidate/donor selection and complex post-transplant management, surgical expertise to perform complex donor and recipient operations, operating room and radiology resources, experienced psychosocial clinicians for assessment and potential ongoing intervention, and programmatic leadership to ensure collaborative care teams.

3.2 | Data gaps and lack of standardization in candidate and donor selection for LDLT

The area with the greatest number of barrier statements across both candidates and donors was in evaluation and selection for LDLT. Statements reflected areas where data were insufficient to clearly permit for standardization or evidence exists but was/is not being uniformly applied in clinical practice. Associated mitigation strategies included areas where significantly more research is needed to appropriately address data gaps and other areas where broader dissemination of existing data should be applied to current clinical decision making.

For candidates, several barriers rated as highly important by conference attendees focused on lack of clinical agreement regarding which candidates to encourage to pursue LDLT. Namely, candidate barriers #2 and #12 on the benefit of LDLT in the context of low MELD, barriers #6 and #11 on survival benefit in HCC with extended HCC criteria, and arguably barrier #13 on whether insurance providers are willing to cover patients with low MELD (Table 1). In selected patients with low MELD-Na (<15), LDLT is associated with improved long-term survival compared to not receiving a transplant and may result in

better long-term graft survival than deceased donor liver transplant.^{14–16} Also, LDLT has shown some benefit to those who are critically ill with acute liver disease, extended HCC criteria, or other severe forms of decompensation in a select group of patients (e.g., no significant infectious history).^{29–31} While a higher MELD score is a good predictor of mortality, accuracy of MELD as the sole predictor of mortality in the lower range (e.g., MELD < 14) is significantly reduced.³² In contrast, the Pediatric End-stage Liver Disease (PELD) score (children <12yr) has good concordance but seriously underestimates actual mortality and is not directly comparable to adults.³³ Decompensating events such as ascites, hepatic encephalopathy, spontaneous bacterial peritonitis, gastrointestinal bleeding, and hepatorenal syndrome are associated with increased mortality, independent of the MELD/PELD score.³⁴ Other clinical factors, such as hypoalbuminemia, malnutrition, and frailty are also predictors of poor waitlist outcomes independent of the MELD/PELD score.^{35,36} Identification of patients who will benefit from LDLT is multifactorial and varies according to the medical presentation of candidates at the time of listing for liver transplant. This comes down to the candidate barrier ranked at #5 emphasizing the need for surgical and medical experience to pre- and post-operatively manage these patients.

A consistent theme across suggested strategies to address barriers in appropriate candidate selection for LDLT was the need for further empirical research. In particular, domains of research focused on better patient selection to optimize patient-outcomes. Many of these statements were rated impactful by consensus conference participants, but with variable agreement on feasibility. However, it would appear that

general recommendations for additional data collection met consensus for feasibility (e.g., candidate barrier #2 strategy “*Continued research is needed to identify patients with low MELD-Na who are at highest risk of waitlist mortality and will benefit from early LDLT*”) whereas strategy statements suggesting research collaborations across multiple groups did not (e.g., candidate barrier #6 strategy “*Further data needed (multi-center data) for better patient selection*”). Other recommended strategies included specific clinical care recommendations (e.g., barrier #2 strategy “*MELD-NA alone should not be used to determine candidacy...*” or barrier #6 on extended HCC criteria strategy “*Achieve response to treatment...*”) and improvements in education for clinical providers, potential candidates, and their families on the benefits of LDLT for select candidates.

In the spectrum of more severe disease including acute liver failure, acute on chronic liver failure, pediatric metabolic diseases, and genetic diseases, experienced centers have shown positive outcomes of LDLT.^{20,29,30} However, careful candidate and donor selection are necessary to ensure optimal post-transplant outcomes. Associated strategy statements outline the need for institutional commitment and resources for urgent presentations that would require rapid evaluations if LDLT were to be pursued. However, there are ethical and safety concerns for the living liver donor in the setting of a candidate with acute liver failure, where expedited evaluations and surgeries performed beyond normal business hours may have fewer resources during these times for optimal donor safety. Additionally, these transplant candidates have a higher mortality rate and potential donors have limited time to understand the full implications of their decisions.³⁰ Finding a suitable living donor in such an urgent situation can be a challenge. Education, evaluation, and consent must be rapid, and many centers do not have the infrastructure to perform expedited evaluations.³⁰ If more transplant centers were to become proficient in broader and safe utilization of LDLT, the combined experience and resources may allow more centers to become able to refine and expedite this process to increase access for some of these candidates. This would require concurrent progress in the optimization of educating the potential living donor appropriately for fully informed consent and infrastructure and resources for rapid donor evaluation.

Alternatively, LDLT for oncologic diseases including hepatocellular carcinoma (HCC) patients beyond Milan criteria and patients with relatively poor or unknown prognosis (e.g., non-resectable colorectal liver metastases, cholangiocarcinoma) is being explored.³⁷⁻³⁹ Data and experience in these subpopulations are limited, impacting provider comfort, and adoption of LDLT across the expanse of the liver transplant waitlist.

Akin to candidate selection, for donor selection there were important areas identified with insufficient data to direct clinical decisions or data exists but has not been consistently integrated into routine clinical care. As presented in Figure 2, clearly determining donor risk at this time still involves significant ‘gray zones’ where relative and absolute risk can be difficult to quantify due to insufficient data and/or inherent limitations of existing data (e.g., substantial selection biases in donor approvals, variability in criteria/cutoffs across centers^{40,41}). This is exemplified by barrier #3 (Table 2), the increasing prevalence of

obesity, metabolic syndrome, and non-alcoholic fatty liver disease (NAFLD) limiting the potential living liver donor pool. Prevalence of obesity, metabolic syndrome, and NAFLD in the US have been reported at 42%, 35%, and 21%, respectively.⁴²⁻⁴⁴ Data suggests that living liver donors with body mass indices (BMIs) between 30 and 35 without metabolic syndromes or significant liver steatosis (<10%) did not result in greater adverse donor or recipient/graft outcomes.⁴⁵ Consensus conference participants agreed a shift from absolute BMI and hepatic steatosis thresholds to an approach focused on risk stratification considering the totality of visceral fat distribution, risk factors for metabolic syndrome, quantification of hepatic steatosis, and fibrosis as appropriate, would be impactful for overcoming this barrier, though consensus was not reached regarding feasibility of this strategy. Alternatively, there was strong sentiment that diabetes, active steatohepatitis, and/or hepatic fibrosis remain reasons for potential living liver donor exclusion.⁴⁶

Several donor barrier statements reflected the need for psychosocial guidelines (Table 2, barrier #4) and psychosocial clinicians with appropriate experience and expertise (Table 2, barriers #9 and #14). Prioritization of research and scholarship into donor psychosocial risks, standardization of the psychosocial evaluation, and clinical decision making in relation to outcomes were considered impactful but did not reach consensus on feasibility. Consistent with other domains of the donor assessment, discussion during the consensus conference noted that a limitation of prior research examining living donor outcomes was the substantial selection bias as potential living liver donors with psychosocial risk factors are less likely to proceed to donation.⁴⁷ The lack of consensus regarding the feasibility of these strategies elucidates general challenges regarding psychosocial phenomena in living donation and organ transplantation. Psychosocial matters tend to be qualitative, multifactorial, diffuse, and of incremental impact to core, quantitative living donation and organ transplantation outcomes.⁴⁸ This means they require *more* data and *more* rigor to fully describe and study their longitudinal impact.

Other components of the medical evaluation of potential LLDs include extensive testing often with low pre-test probability in otherwise healthy individuals (e.g., Table 2, barrier #13). This can lead to abnormal test results of unclear significance for a disease of low incidence and/or abnormal test results which define a clinical condition of unclear attributable risk with donation. As indicated from donor barrier #5 (Table 2), consensus was met that expansion of donor acceptance rates will at least partially rely on an improved understanding of variability across center-level donor evaluation processes, including testing and reasons for rule out. Strategies focused on such data collection were noted to be of high potential impact and generally feasible. However, barrier statements and strategies addressing specific testing were generally prioritized low. For example, it was recognized that hypercoagulable testing is widely variable between centers and the significance of results are not always clear,^{49,50} but consensus for testing strategy was not ranked of high impact or feasibility (Table 2, barrier #8). Similarly, LLD candidates who are heterozygous alpha-1-antitrypsin carriers⁵¹ or found incidentally to have hemosiderosis

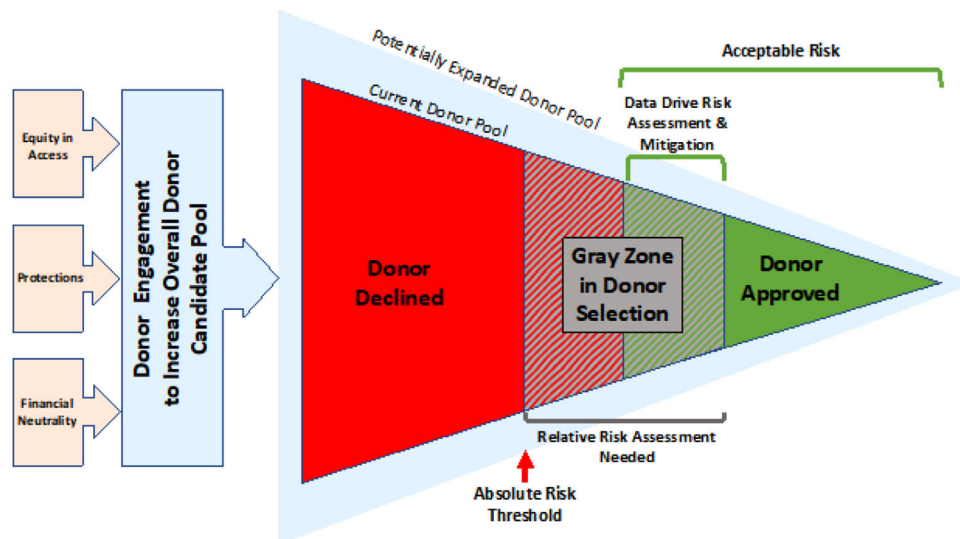


FIGURE 2 Increasing donor engagement and refining donor selection approach to expand LDLT.

(without primary iron overload)⁵² may proceed with donation, but these specific recommendations were not noted to be highly impactful regarding the broad expansion of LDLT in the US (Table 2, barriers #16 and #17). This was also evident regarding responses related to testing/screening of adult relatives as potential LLDs for children with rare genetic disease (Table 2, barrier #15).

3.3 | Data gaps regarding post-living liver donation outcomes and resource needs

While few barriers explicitly stated/outlined long-term post-transplant outcomes, long-term monitoring was identified across numerous mitigation strategies to improve our understanding of risk stratification. However, one barrier explicitly outlining post-living donation barriers identified the financial burden incurred by living liver donors that was rated as the most important barrier to overcome as a transplant community (Table 2, barrier #1). Living liver donors report significant financial burden from donation⁵³ which could ultimately deter those with limited income from donating. The National Living Donor Assistance Center (NLDAC) has been developed to offset these out-of-pocket costs⁵⁴ reducing burden on vulnerable liver waitlist registrants and their living donor candidates. The strategy ranked as most impactful and feasible for overcoming potential financial barriers is for transplant centers to review and optimize NLDAC application processes by integrating them in formalized workflows. Examples given during the conference included providing information about NLDAC on center webpages, in donor evaluation consent forms, and incorporating standard process for independent living donor advocates (ILDAs) and transplant social workers to discuss NLDAC with every waitlist registrant and potential living donor. Other strategies suggested to reduce the financial burden on potential LLDs included translating protections available to kidney paired exchange donors such as Donor Shield⁵⁵ to LLDs, which was rated as highly impactful by the consensus conference

participants. However, implementing these strategies was noted to be challenging and thus feasibility was not ranked highly.

Several donor barrier statements focused on lack of knowledge regarding long-term positive and negative psychosocial implications of living donation (donor barriers #7 and #11) or psychological effect of donor ineligibility (donor barrier #10). While the Adult-to-Adult Living Donor Liver Transplantation Cohort Study (A2ALL) provided important insights and data on predictors of longer-term psychosocial outcomes, for example Butt et al.,⁵⁶ significantly greater data with longer follow-up would be beneficial as well as assessment of individuals who were ineligible to donate.

4 | SUMMARY AND NEXT STEPS

LDLT has the strong potential to significantly impact the ongoing organ shortage and reduce waitlist mortality while still balancing donor safety and well-being. However, willingness to embrace LDLT as a viable option for an expandingly eligible cohort of individuals in need of liver transplantation remains a significant barrier to broader implementation. As outlined above, there are steps that need to occur to begin to address these barriers. First, collaborative efforts both across and within organizations, including between pediatric programs and their associated LDLT programs, should occur to develop education and outreach programs for providers on the benefits of LDLT for potential candidates with indications previously thought to be prohibitive for LDLT. There needs to be improved data as to which low MELD patients should proceed with LDLT and how to optimize our sickest patients for success with LDLT. In addition, more data are needed on pediatric specific diseases and clinical factors, including metabolic/genetic diseases, ABO incompatibility, malnutrition, and acute liver failure, which would have success with LDLT. Importantly, for donors, evidence has grown in certain areas allowing for improved understanding of evidence-based attributable risk stratification and mitigation. However, there are also

areas where appropriate restrictions should remain as they are associated with greater donor risk (e.g., metabolic syndrome, diabetes, active steatohepatitis, and/or hepatic fibrosis). Multicenter studies are needed to continue to improve both candidate selection and to improve on donor risk stratification, which could contribute to broader standardization of candidate and donor evaluation and selection across centers. Ultimately, this will need to be continuously evaluated to ensure potential benefits to the candidate are closely balanced against the risk of the potential living donor. Though this requires a shift from absolute donor risk avoidance to relative risk assessment with appropriate mitigation. Lastly, while much has been learned from the living kidney donor population, there is still considerable growth needed in progressing living liver donation and factors unique to liver transplant candidates that will require study, as liver disease encompasses unique factors that need to be addressed, including the stigma associated with liver disease. Therefore, we recommend empirical evaluation of targeted interventions with liver transplant candidate and donor populations, engaging broader support networks including the American public and consistent institutional commitment and resources.

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CONFLICT OF INTEREST STATEMENT

The author of this manuscript have conflicts of interest to disclose as described by Clinical Transplantation. Dr. Levitsky is an advisor for Eurofins, grant funding from Eurofins, and is an Advisor for Novartis. Dr. Pillai is on the Medical Advisory Board for Eisai Inc, Exelixis, Astrazeneca, Genentech, and Replimune. All other authors have no relevant disclosures. This manuscript was the result of a broader multidisciplinary consensus conference, though no outside authors were involved with the preparation of this analyses or the manuscript prior to publication. Michelle T. Jesse: None related to this manuscript; Whitney E. Jackson: None related to this manuscript; AnnMarie Liapakis: None related to this manuscript; Swaytha Ganesh: None related to this manuscript; Abhinav Humar: None related to this manuscript; Nicolas Goldaracena: None related to this manuscript; Josh Levitsky: Advisor for Eurofins, Grant funding from Eurofins, Speaker for Mallinckrodt, Advisor for; eGenesis, DSMB for Quell; David Mulligan: None related to this manuscript; Elizabeth A. Pomfret: None related to this manuscript; Daniela P. Ladner: None related to this manuscript; John P. Roberts: None related to this manuscript; Alisha Mavis: None related to this manuscript; Carrie Thiessen: None related to this manuscript; James Trotter: None related to this manuscript;

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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